REMARKS

Upon entry of this paper, claims 1, 3, 15-19, 21-26, 28, 37-41 and 75 have been amended and claims 5-11, 13, 14, 20, 32-36, 42-72, 74, 76-78 and 80-85 cancelled (without prejudice or disclaimer). Thus, claims 1-4, 12, 15-19, 21-31, 37-41, 73 and 75 are presently pending in this application.

Allowable Subject Matter

Applicants kindly thank Examiner Morris for acknowledging that Claim 1 would be allowable if rewritten to overcome the rejections under 35 U.S.C. § 112 and if rewritten directed solely to the subject matter indicated as being examined.

Applicants also thank Examiner Morris for acknowledging that Claims 3, 4, 7, 14, 15, 17, 19, 22-26, 37-39, 41, 73 and 75-78 would be allowable if rewritten to overcome the rejections under 35 U.S.C. § 112 and to include all of the limitations of the base claim and any intervening claims and if rewritten to be directed solely to the elected compounds.

Applicants also thank Examiner Morris for acknowledging that Claims 2, 5, 6, 12, 16-18, 21, 27-31 and 40 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and if rewritten to be directed solely to the elected compounds.

Claim Amendments

Claim 1 has been amended, as suggested by Examiner Morris, to overcome the rejections under 35 U.S.C. § 112 and to be directed solely to the subject matter indicated as being examined. Specifically, Claim 1 has been amended to provide that D is optionally substituted pyrrolidine, wherein X is attached to the N of the pyrrolidine ring, X is (CO)), A is optionally substituted benzyl or phenyl, Z is alkylene, G is optionally substituted pyridine-2-yl, Y is O-CH_n-NH-$(CH_2)_n$, B represents non-heterocyclic groups and n is as set forth in claim 1.

Generally, claims 1, 3, 15-19, 21-26, 28, 37-41 and 75 have been amended to overcome the rejections under 35 U.S.C. 112 and to place the application in condition for allowance, as suggested by Examiner Morris and as discussed in further detail below.

I. Rejections under 35 USC § 112, First Paragraph

Rejection of Claim 75

Claim 75 stands rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor had possession of the claimed invention at the time the application was filed. Specifically, the Office Action alleges that there is a lack of description as to how the forms such as the hydrates or solvates are produced and what hydrates or solvates are produced in the specification.

Applicants respectfully disagree with the present rejection; however, solely for the purpose of expediting prosecution, Applicants have amended the claims to remove the references to the phrase "solvates". Applicants respectfully submit that claim 75, as amended, even more clearly conveys to one skilled in the relevant art that the Applicants had possession of the claimed invention at the time the application was filed.

Reconsideration and withdrawal of the rejection of claim 75 under 35 USC § 112, first paragraph, are respectfully requested.

Rejection of Claims 1, 7, 14, 15, 22-26, 37 and 39

Claims 1, 7, 14, 15, 22-26, 37 and 39 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Office Action alleges that the expressions "substituted" and "derivatives" are employed with considerable abandon and that the specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation.

Applicants respectfully disagree. Nevertheless, without acquiescing to any basis of the rejection, and solely to expedite prosecution and allowance of the application, Applicants have amended Claims 1, 7, 14, 15, 22-26, 37 and 39 to remove all references to the phrase "derivatives". By way of the present amendment, Applicants have hereby cancelled claims 7 and 14; thus, any rejections with respect to these claims are rendered moot.

A disclosure "is sufficient if the disclosure teaches those skilled in the art what the invention is and how to practice it." *In re Grimme*, 124 U.S.P.Q. 449, 502 (C.C.P.A. 1960).

Applicants respectfully submit that the guidance provided throughout the Specification, and in particular in at least paragraphs [0273-0291] would sufficiently enable one skilled in the relevant art to make and/or use the claimed substituted compounds. For example, paragraphs [0273-0283] of the instant Specification define usage of the chemical groups"alkyl", "cycloalkyl", "alkenyl", "cycloalkenyl", "alkynyl", "aryl", "heteroaryl", and "heterocycl", as well as what substituted versions of these chemical groups entails. Moreover, paragraphs [0289-0291] specifically define "substituted" and the types of substituents that can be used to sufficiently guide a person of ordinary skill in the art as to how make and use the compounds containing such substitutions without undue experimentation. For example, rather than failing to give indication as to what the substituted groups really are as alleged by the Office Action (*See*, e.g., page 7), paragraph [0291] specifically provides such indications to those skilled in the art by stating that the substituents can be selected from any of the groups, moieties and substituents disclosed in the specification. The specification provides further guidance by specifying that the substituents are preferably selected from the group of hydroxyl, alkoxy, mercapto, cycloalkyl, heterocyclic, aryl, heteroaryl, aryloxy, etc. (*Id.*) Applicants respectfully submit that based upon such guidance, a person of skill in the art would understand what the invention is and how to practice it, i.e., to readily ascertain the scope of the claimed substituted compounds and to be able to synthesize such compounds without undue experimentation.

For at least the foregoing reasons, Applicants respectfully submit that the guidance provided in these paragraphs and throughout the specification would enable a person of ordinary skill in the art to make and use the claimed substituted compounds without requiring undue experimentation. Reconsideration and withdrawal of the 35 U.S.C. § 112 rejection are respectfully requested.

II. Rejections under 35 USC § 112, Second Paragraph

Claims 1, 3, 4, 7, 14, 15, 17, 19, 22-26, 37-39, 41, 73 and 75-78 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to distinctly claim the subject matter which the Applicants regard as their invention. Specifically, the Office Action alleges that the expressions "substituted" and "derivatives" are indefinite to their meaning. The Office Action also alleges that the expression "solvate" in claim 75 is indefinite. The Office Action also alleges that the phrases "preferably" and "more preferably" render claims 1, 22, 37 and 39 indefinite because it is unclear whether the limitations following the phrase are part of the

claimed invention. The Office Action also alleges that claims 77 and 78 are indefinite because they merely recite a use without any active, positive steps delimiting how this use is actually practiced. The Office Action also alleges that claim 76 is indefinite since it is unclear how a composition can contain a single dose and multiple doses at the same time.

Applicants respectfully disagree. Nevertheless, without acquiescing to any basis of rejection, and solely to expedite prosecution and allowance of the application, Applicants have:

- cancelled claims 7, 14 and 76-78, thereby rendering any rejection of these claims moot;
- amended the presently pending claims to remove all references to the phrase "derivatives";
- amended claim 75 to remove the limitation "solvate"; and
- amended claims 1, 22, 37 and 39 to remove all recitations of the phrases "preferably" and "more preferably".

The remarks above with respect to the 35 U.S.C. § 112, first paragraph enablement rejection of Claims 1, 7, 14, 15, 22-26, 37 and 39 are equally applicable in the context of 35 U.S.C. § 112, second paragraph. Specifically, Applicants respectfully submit that the recitation of the phrase "substituted" in the presently pending claims is not indefinite because such phrase is clearly defined in an unambiguous manner in the Specification in at least paragraphs [0273-0291]. Specifically, as noted above, the specification defines what the phrase "substituted" means with respect to each chemical group recited in the claims e.g., "substituted alkyl" is defined in paragraph [0273], "substituted cycloalkyl" is defined in paragraph [0274], etc. Moreover, as also noted above, paragraph [0292] of the Specification unambiguously defines the types of substituents which can be used in the recited "substituted" groups and thus there is certainty with respect to their scope. For at least the foregoing reasons, Applicants respectfully submit that claims 1, 3, 4, 15, 17, 19, 22-26, 37-39, 41, 73 and 75 as amended are unambiguous and distinctly claim the subject matter that the Applicant regards as his invention, and that there is certainty with respect to their scope (MPEP § 2171). In view of the foregoing, reconsideration and withdrawal of the rejected claims 1, 3, 4, 15, 17, 19, 22-26, 37-39, 41, 73 and 75 under 35 USC § 112, second paragraph are respectfully requested.

III. Rejection of Claims 77 and 78 under 35 U.S.C. § 101

Claims 77 and 78 stand rejected under 35 U.S.C. § 101 because the recitation of a use, without setting forth any steps involved in the process, allegedly results in an improper definition

of a process. Applicants note that claims 77 and 78 have been cancelled by way of the present amendment, thereby rendering the subject rejection moot.

CONCLUSION

In view of the above remarks and amendments, Applicants respectfully submit that the application is in condition for allowance. If the Examiner believes that a telephone call would be useful in expediting the allowance of the application, the Examiner is invited to contact the undersigned.

Applicants believe that no fee is due for the response other than the fees provided for herewith. However, if an additional fee is due, please charge Deposit Account No. 50-3655, from which the undersigned is authorized to draw, under order number SHIR-Jerini-J10030US

Dated: 6/3/11

Respectfully submitted,

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